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| 10/633,501 | 08/05/2003 | Uri Amin | 1335VAS-US | 5179 |

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Dekel Patent Ltd.
Beit HaRofim
Room 27
18 Menuha VeNahala Street
Rehovot,
ISRAEL

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| EXAMINER |
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HOFFMAN, MARY C

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| ART UNIT | PAPER NUMBER |
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3733

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,501

Applicant(s)

ARNIN ET AL.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-15 in the reply filed on 07/27/2006 is acknowledged.

Claims 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/27/2006.

Drawings

The drawings are objected to because the drawings are informal and because of the reasons outlined on the attached PTO-948. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top

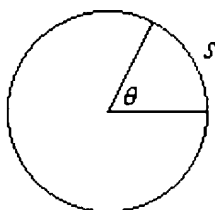
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margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities:

The term "articulating surface subtends an arc" in claim 1 is used to mean "articulating surface subtends an angle". In geometry, an arc "subtends" an angle θ ; literally, "stretches under." The claim would be clearer if the claim were corrected to say --articulating surface is an arc that subtends an angle--.



IT IS CONVENTIONAL to let the letter s (for *space*) symbolize the length of an arc, which is called arc length. We say in geometry that an arc "subtends" an angle θ ; literally, "stretches under."

Now the circumference of a circle is an arc length. And the ratio of the circumference to the diameter is the basis of radian measure. That ratio is the definition of π .

<http://www.themathpage.com/aTrig/arc-length.htm>

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Garber (U.S. Patent No. 5,725,587).

Garber discloses an elastomeric cover (col. 1, lines 8-20) having a seamless articulating surface which is at least part of a three-dimensional curved surface, wherein a cross-section of a portion of said seamless articulating surface is an arc that subtends an angle greater than 180 degrees (FIG. 2). The seamless articulating surface comprises a portion of a sphere greater than a hemisphere. The cover comprises a seam on the non-articulating surface. The non-articulating surface comprises an inner surface adapted to contact an outer surface of a rigid implant. The non-articulating surface comprises an inner surface of said elastomeric cover adapted to contact an outer surface of rigid part of an orthopedic implant. Claim 3 discloses a "mold-parting seam" and claim 10 discloses that the elastomeric cover is produced by at least one of injection molding and blow molding, and these are being considered as product by process claims. In a product by process claim, if the applied reference reasonably indicates that a product disclosed therein is the same or substantially the same as the claimed product, the burden shifts to the applicant to provide evidence to the contrary.

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The elastomeric cover has a smooth surface (FIG. 7). The elastomeric cover has a non-smooth surface (porous, col. 7. lines 23-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garber (U.S. Patent No. 5,725,587).

Garber discloses the claimed invention except for a thickness in a range of about 1 mm to about 4 mm, a material hardness in a range of about 60 Shore A to about 95 Shore A, and an elastic modulus in a range of about 10 to about 150 MPa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Garber having a range of about 1 mm to about 4 mm, a material hardness in a range of about 60 Shore A to about 95 Shore A, and an elastic modulus in a range of about 10 to about 150 MPa, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garber (U.S. Patent No. 5,725,587) in view of Dunlap et al. (U.S. Patent No. 5,167,968).

Garber discloses the claimed invention except for the cover having extraneous material that is removable.

Dunlap et al. disclose that extraneous material, or excess material, is typically left behind in blow molding applications, and in order to finish the blow mold, the excess material needs to be removed (col. 1).

It would have been obvious that the device of Garber et al. have extraneous material that is removable in view of Dunlap et al. because it is well known in the art of blow molding that extraneous material remains after something is molded and the extraneous portion needs to be removed this in order to finish the blow mold.

If Applicant argues that the device of Garber is not seamless although the seam is not shown in the diagrams, then claims 1-4 and 7-13 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Garber (U.S. Patent No. 5,725,587) in view of Schuessler (U.S. Patent Applicant Publication 2003/0018387).

Garber discloses an elastomeric cover (col. 1, lines 8-20) having an articulating surface which is at least part of a three-dimensional curved surface, wherein a cross-section of a portion of said seamless articulating surface is an arc that subtends an angle greater than 180 degrees (FIG. 2). The articulating surface comprises a portion of a sphere greater than a hemisphere. The cover comprises a seam on the non-articulating surface. The non-articulating surface comprises an inner surface adapted to contact an outer surface of a rigid implant. The non-articulating surface comprises an inner surface of said elastomeric cover adapted to contact an outer surface of rigid part

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of an orthopedic implant. Claim 3 discloses a "mold-parting seam" and claim 10 discloses that the elastomeric cover is produced by at least one of injection molding and blow molding, and these are being considered as product by process claims. In a product by process claim, if the applied reference reasonably indicates that a product disclosed therein is the same or substantially the same as the claimed product, the burden shifts to the applicant to provide evidence to the contrary. The elastomeric cover has a smooth surface (FIG. 7). The elastomeric cover has a non-smooth surface (porous, col. 7. lines 23-26).

Garber discloses the claimed invention except for the articulating surface being seamless and the cover having a thickness in a range of about 1 mm to about 4 mm, a material hardness in a range of about 60 Shore A to about 95 Shore A, and an elastic modulus in a range of about 10 to about 150 MPa.

Schuessler discloses a system for molding shells of medical implants to eliminate undesirable seams (paragraph [0014]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made construct the device of Garber using the system of Schuessler in order to eliminate undesirable seams. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Garber in view of Schuessler having a range of about 1 mm to about 4 mm, a material hardness in a range of about 60 Shore A to about 95 Shore A, and an elastic modulus in a range of about 10 to about 150 MPa, since it has been held that where the

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general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garber (U.S. Patent No. 5,725,587) in view of Schuessler (U.S. Patent Applicant Publication 2003/0018387) and further in view of Dunlap et al. (U.S. Patent No. 5,167,968).

Garber discloses the claimed invention except for the cover having extraneous material that is removable.

Dunlap et al. disclose that extraneous material, or excess material, is typically left behind in blow molding applications, and in order to finish the blow mold, the excess material needs to be removed (col. 1).

It would have been obvious that the device of Garber et al. in view of Schuessler have extraneous material that is removable in view of Dunlap et al. because it is well known in the art of blow molding that extraneous material remains after something is molded and the extraneous portion needs to be removed this in order to finish the blow mold.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER